Introduction

Vertebral axial decompression is a type of traction for the low back. The idea is to stretch the spine. This stretching is intended to create more space between the bones of the spine (the vertebrae) to relieve pressure on damaged discs. The goal is to relieve low back pain caused by damaged discs or other problems with the vertebrae or tissues. This service is investigational (unproven). There are not enough high-quality published medical studies to determine whether this treatment is effective.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Investigational</th>
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<tbody>
<tr>
<td>Vertebral axial decompression</td>
<td>Vertebral axial decompression is considered investigational.</td>
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</table>
Vertebral axial decompression applies traction to the vertebral column to reduce intradiscal pressure and, in doing so, potentially relieves low back pain associated with herniated lumbar discs or degenerative lumbar disc disease.

Background

Vertebral axial decompression (also referred to as mechanized spinal distraction therapy) is used as traction therapy to treat chronic low back pain. Specific devices that are available are described in the Regulatory Status section. In general, during treatment the patient wears a pelvic harness and lies prone on a specially equipped table. The table is slowly extended, and a distraction force is applied via the pelvic harness until the desired tension is reached, followed by a gradual decrease of the tension. The cyclic nature of the treatment allows the patient to withstand stronger distraction forces compared with static lumbar traction techniques.
individual session typically includes 15 cycles of tension, and 10 to 15 daily treatments may be administered.

Summary of Evidence

For individuals who have chronic lumbar pain who receive vertebral axial decompression, the evidence includes randomized controlled trials (RCTs). Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Evidence for the efficacy of vertebral axial decompression on health outcomes is limited. Because a placebo effect may be expected with any treatment that has pain relief as the principal outcome, RCTs with sham controls and validated outcome measures are required. The only sham-controlled randomized trial published to date did not show a benefit of vertebral axial decompression compared with the control group. The evidence is insufficient to determine the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in March 2017 did not identify any ongoing or unpublished trials that would likely influence this policy.

Practice Guidelines and Position Statements

No guidelines or statements were identified that recommend this treatment.

Medicare National Coverage

Medicare has issued a national noncoverage policy (160.16) for vertebral axial decompression in 1997.6

Regulatory Status

Several devices used for vertebral axial decompression have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. Devices include the VAX-
D®, Decompression Reduction Stabilization (DRS®) System, Accu-SPINA® System, DRX-3000®, DRX9000®, SpineMED Decompression Table®, Antalgic-Trak®, Lordex® Traction Unit, and Triton® DTS. According to labeled indications from the FDA, vertebral axial decompression may be used as a treatment modality for patients with incapacitating low back pain and for decompression of the intervertebral discs and facet joints.

FDA product code: ITH

References


History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
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<tr>
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<td>Replace policy - Policy reviewed with literature search; no change in policy statement. VAX-D added to title.</td>
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<td>10/09/07</td>
<td>Replace policy - Policy updated with literature review; no change in policy statement. Reference update and addition.</td>
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<td>10/14/08</td>
<td>Replace policy - Policy updated with literature search; no change to the policy statement. References added.</td>
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<td>12/08/09</td>
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<td>11/10/11</td>
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<tr>
<td>12/19/12</td>
<td>Replace policy. Policy updated with literature search through August 2012; references reordered; policy statement unchanged.</td>
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<td>12/09/13</td>
<td>Replace policy. Policy reviewed. Policy Guidelines reformatted for readability. A literature search through August 22, 2013 did not prompt a revision of the references. Policy statement unchanged. CPT code 97012 removed; it is not specific to this policy.</td>
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<td>01/21/14</td>
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<tr>
<td>12/17/14</td>
<td>Annual Review. Policy updated with literature review through September 15, 2014; policy statement unchanged. ICD-10 diagnosis and procedure codes removed; these do not relate to policy adjudication.</td>
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<td>12/08/15</td>
<td>Annual Review. No change to policy statement. No references added.</td>
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<td>06/01/16</td>
<td>Annual Review, approved May 10, 2016. Policy reviewed. A literature search through April 28, 2016 did not prompt a revision of the references. No change to the policy statement.</td>
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**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2017 Premera All Rights Reserved.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to
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Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:
- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost.

Call 800-722-1471 (TTY: 800-842-5357).

阿拉伯 (Arabic):
这个通知含有重要信息。这个通知可能含有有关您申请或通过Premera Blue Cross获得的盖章的可能的重要信息。这个通知可能含有重要的日期。您可能需要在截止日期之前采取行动，以保留您的健康保险或帮助费用。您有权免费得到您的母语的通知和帮助。拨打电话 800-722-1471 (TTY: 800-842-5357)。

中文 (Chinese):
本通知有重要的訊息。本通知可能有關於您透過Premera Blue Cross提交的申請或保險的重要訊息。本通知可能含有重要的日期。您可能需要在截止日期之前採取行動，以保留您的健康保險或費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357)。

Français (French):

Kreyòl ayisyen (Creole):
Avi sila a gen enfòmasyon enpòtan ladan. Avi sila a kapab genyen enfòmasyon enpòtan konsèn a apikasyon w lan oswa konsèn kouvèti asirans lan atravé Premera Blue Cross. Kapab genyen dat ki enpòtan nan avi sila a. Ou ka gen pou pran kèk aksyon avan sèten dat limit pou ka kenbe kouvèti asirans sante w la oswa pou yo ka ede w avèk depans yo. Se dwa w pou resewa enfòmasyon sa a ak assistans nan lang ou pale a, san ou pa gen pou peyeye pou sa. Rate nan 800-722-1471 (TTY: 800-842-5357).

Deutsche (German):

Hmoob (Hmong):

Ilok:lo (Ilocano):
Daytoy a Pakdaar ket naglao iti Napateg nga Impormasion. Daytoy a pakdaar mabalin nga adda ket naglao iti napateg nga impormasion maipanggep iti apikasyonu woye coverage babu a. Premera Blue Cross. Daytoy ket mabalin dagiti importante a pelsa iti daytoy a pakdaar. Mabalin nga adda rumbeng nga aramideng nga adda sakyay dagiti partiklar a naituding nga adda alaw tapo mapagmalalnedyo ti coverage ti salun-ayyo woye tulong kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tulong ti bukodyo a pagasasao nga awan ti bayadanyo. Tumawg ti numero nga 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):

프랑스어 (French): Vous avez le droit d'obtenir cette information en votre langue et gratuitement. Pour maintenir votre couverture de santé ou votre assistance prévotice à des coûts, vous devez les dates clés. Veuillez prendre note de ces points pour vous assurer que vous prenez les mesures nécessaires à temps. Vous pouvez obtenir cette information et assistance en français à tout moment. Appelez le 800-722-1471 (TTY: 800-842-5357).

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lenmiş (Punjabi): ਨੀਆਂ 800-722-1471 (ਟੀਐਟੀ: 800-842-5357) ਵਿੱਚ ਕੌਮਾਲੀਆਂ ਲਿਖ ਦੇ ਸਕਦੀ ਹੈ। ਹੌਲੀ ਨੋਟਿਸ਼ਨ ਮਾਇਟੀ ਸੋਚਾ ਜਾਂ ਸੋਚਨ ਵਿੱਚ ਰੱਖਣਾ ਪ੍ਰੀਮਰਾ ਬ੍ਰੂਲੁਸ ਕ੍ਰੁਸ ਦੁਆਰਾ ਸੂਚਿਤ ਹੋਵੇਗਾ ਜਦੋਂ ਕਿ ਕੁਝ ਰੱਖਾ ਜਾਣਵਾਤਾ ਹੈ। 800-722-1471 (5357) ਵਿੱਚ ਕੌਮਾਲੀਆਂ ਲਿਖ ਦੇ ਸਕਦੀ ਹੈ।

Español (Spanish): Este Aviso contiene información importante. Es posible que este aviso contenga información importante. Conteste a su solicitud. La cobertura a través de Premera Blue Cross. Es posible que haya fechas claves en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).


تاء (Thai): ประกาศฉบับนี้มีข้อมูลสำคัญที่เกี่ยวกับการให้บริการเคียงข้างเคียงของบริการสุขภาพของคุณ Premera Blue Cross และบริการที่มีอยู่ในสถานะปัจจุบัน คุณควรดูด้วยใจเนื่องจากในกรณีที่มีการเปลี่ยนแปลงที่สำคัญจะกระทบกับการประกันสุขภาพของคุณ คำนึงถึงที่มีความชัดเจนที่มีอยู่ใน ประกาศฉบับนี้ มีข้อมูลที่อาจมีผลกระทบต่อการช่วยเหลือของคุณ 800-722-1471 (TTY: 800-842-5357).